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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,387	12/19/2005	Rita Boge Andersen	05198-P0006A	5168
24126 7590 10/26/2010 ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET STAMFORD, CT 0/005 5/(10)			EXAMINER	
			DEES, NIKKI H	
STAMFORD, (	STAMFORD, CT 06905-5619		ART UNIT	PAPER NUMBER
			1781	
			MAIL DATE	DELIVERY MODE
			10/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/520,387	ANDERSEN ET AL.			
		Examiner	Art Unit			
		NIKKI H. DEES	1781			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)[\	Responsive to communication(s) filed on 10 Se	entember 2010				
· · · · · · · · · · · · · · · · · · ·	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.					
′=	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
٥/ك	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
	closed in accordance with the practice and i	x parte gadyle, 1000 C.D. 11, 10	0.0.210.			
Dispositi	on of Claims					
4)🛛	☑ Claim(s) <u>1,3-14,16-20 and 23-34</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)	5) Claim(s) is/are allowed.					
6)🛛	6)⊠ Claim(s) <u>1,3-14,16-20 and 23-34</u> is/are rejected.					
7)	Claim(s) is/are objected to.					
8)□	Claim(s) are subject to restriction and/or	· election requirement.				
Application Papers						
9)□	The specification is objected to by the Examine	r				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<u>.</u>						
	12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:					
	1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No					
	3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachmen	t(s)					
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da				
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application 6) Other:						

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## **DETAILED ACTION**

1. The amendment filed September 10, 2010, has been entered. Claims 1, 3-14, 16-20 and 23-34 are currently pending in the Application. Claims 2 and 15 have been cancelled. The previous objections to claims 23 and 31 have been withdrawn in view of the amendments to claims 23 and 31. The previous 112 rejections of claims 2 and 15 have been withdrawn in view of the cancellation of claims 2 and 15. The previous 112 rejections of claims 20 and 23 have been withdrawn in view of the amendments to claims 20 and 23.

2. The Examiner notes that the header for the claims and the remarks refers to an incorrect application serial number. The claims and remarks submitted pertain to the instant application.

#### Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 1 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Claim 1 claims a first part of gum base granules and a second part of gum base granules comprising "conventional" gum base. It is unclear what differentiates the

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"conventional" gum base granules of the second part from the gum base granules of the first part. It is understood that the granules of the second part need not comprise flavor or active ingredients, but it is unclear what other differences the "conventional" description is intended to encompass.

6. Claim 25 claims a "conventional" gum base. As with claim 1, it is unclear how the conventional gum base is different from the gum base comprising the flavor and/or active ingredients.

## Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 1, 3-6, 8-11, 14, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang (EP 0 221 850).
- 9. Regarding claims 1, 3, 4, and 8-11, Yang teaches compressed chewing gum tablets composed of granules including synthetic elastomer gum base, e.g. polyvinylacetate, or natural elastomer gum base (i.e. natural resin) (col. 8 line 47-col. 9 lines 14). Yang teaches a tablet may be made by blending two or more granulations before compressing, wherein at least one contains a flavorant (col. 11 lines 49-65). Though Yang does not speak to tackiness moderation, the presence of the natural resin

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meets the limitations of claims 8, 9 and 11 and it is considered inherent that it would affect the tackiness moderation as claimed.

- 10. Regarding claim 5 the presence of any of wax (col. 9 lines 14-21), compression aid, lubricant, anti-adherent and glidant is optional, and thus, may or may not be present.
- 11. Regarding claim 6, Yang teaches the water content in their tablet of 2-5% (col. 2 lines 24-26).
- 12. Regarding claim 14, Yang teaches flavors in the composition at about 1 to 10% by weight (col. 10 lines 30-34).
- 13. Regarding claim 20, Yang teaches sweeteners in the tablet in an amount preferably from 60-98% bulk sweetener, with additional amounts of high-intensity sweetener (col. 9 lines 32-65). As this range significantly overlaps Applicant's claimed range, it is considered to anticipate the claim.

## Claim Rejections - 35 USC § 103

- 14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 15. Claims 7, 12, 13, 16-19, and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (EP 0 221 850).

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16. Regarding claim 7, Yang teaches compression compounds over a range of 0.1% to 5%, and states that the range will vary broadly (col. 10 lines 21-23). One of ordinary skill would have found it obvious to provide a gum center substantially free of compression compounds if it was not desired to use a large amount of the compounds. Yang teaches that a smaller particle size increases the efficiency of the compression compounds. One of ordinary skill, through no more than routine experimentation, would have been able to determine the minimum amount of compression aid to use.

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- 17. Regarding claims 12 and 13, Yang teaches natural resins and elastomers for use in the gum base (col. 8 line 47-col. 9 line 13). As it is well known to vary elastomers and natural resins in chewing gum compositions, one of ordinary skill would have been able to arrive at the desired texture through no more than routine experimentation with the amounts of natural resins and elastomers.
- 18. Regarding claims 16-19 and 34, as Yang teaches that all of the claimed components may or may not be present in the chewing gums. The determination of the optimum amount of each component in the gum tablet would require nothing more than routine experimentation by one reasonably skilled in this art (col. 9 lines 14-26). Further, it would have been obvious to use the magnesium stearate as a lubricant in the outer layer of the tablets since the purpose of the magnesium stearate is to reduce friction between the inner die wall and the tablet edge during ejection and to prevent capping (col. 10, lines 3-8)
- 19. Regarding claims 25-33, as the granules of Yang may comprise the natural and/or synthetic resins as detailed above, and at least two different granulates are

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combined in the compressed chewing gum tablet, the combination of two different granules comprising different elastomers, resins, flavors, etc. is considered to be obvious over the teachings of Yang.

- 20. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Athanikar et al. (6,322,828).
- 21. Athanikar et al. teach a method where a flavor is incorporated into a gum base (col. 4 lines 14-21). The gum base is then granulated in the presence of sweeteners and active ingredients (col. 3 lines 20-26; claim 1). The granulated composition is compressed into tablets (col. 7 lines 40-44).
- 22. Regarding the mixing of an elastomer and elastomer plasticizer to form a gum base, one of ordinary skill would have recognized that the synthetic elastomers of Athanikar et al. taught to be used in the gum base (col. 4 lines 21-25) are most commonly provided in combination with an elastomer plasticizer, and would have found it obvious to do so.
- 23. Athanikar et al. do not specifically refer to their sweeteners as bulk sweeteners. However, one of ordinary skill would have recognized that bulk sweeteners are commonly used in chewing gum products and would have found it obvious to utilize a bulk sweetener where the prior art teaches sweetener.
- 24. Athanikar et al. are silent as to the blending of a first and second gum base during the addition of further additives.

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25. One of ordinary skill would have found it obvious to blend a first granulated gum base as taught by Athanikar et al. with a second granulated gum base as taught by Athanikar et al. to provide a tabletted chewing gum comprising two different active ingredients. The blending of the first and second chewing gum bases is considered to be a duplication of parts and would have been expected to provide the predictable result of a chewing gum comprising two different active ingredients.

## **Double Patenting**

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 1, 3-14, 16-20 and 25-34 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-

5, 8-12, 14-19, and 32 in copending Application No. 10/520,173. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to select any additives, including sweeteners and flavors, to be included in the gum center of the claims in 10/520,173 and for the barrier layer in the claims of 10/520,173 to fully encapsulate the gum center simply depending upon desired results, personal appeal and consumer preference.

- 28. This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
- 29. Claims 1, 3-14, 16-20 and 25-34 are further provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 in copending Application No. 11/028,684. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to include sweeteners and flavors in the gum granules and compressed gum tablets in the claims of 11/028,684 since it is well known to prepare chewing gum products which include sweeteners and flavors.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

30. Claims 23 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-31 of copending Application No. 10/520,173 in view of Athanikar et al. (6,322,828) and Yang.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to prepare two groups of gum granules as taught by Athanikar and then blend the two groups and compress them in the claimed method of 10/520,173 since it is well known to prepare a chewing gum tablet by such a technique.

This is a <u>provisional</u> obviousness-type double patenting rejection.

# Response to Arguments

- 31. Applicant's arguments filed September 10, 2010, have been fully considered but they are not persuasive.
- 32. Applicant argues that a "conventional" gum base is defined in the specification and one of ordinary skill would have understood what the claim is intended to encompass (Remarks, p. 9).
- 33. This argument is not persuasive. Applicant's specification at p. 2 lines 23-25, teaches that a conventional gum base "comprises" water insolvent parts, and has not been mixed with flavors or active ingredients. The use of "comprises" indicates that the gum base may comprise other unrecited elements, including water soluble ingredients. Therefore, the constitution of a "conventional" gum base is not defined, as Applicant alleges.

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34. Applicant argues that Yang does not teach at least two different gum base granules where one part comprises conventional gum base (Remarks, pp. 11-12).

- 35. This argument is not persuasive. While Applicant's specification teaches that conventional gum base refers to gum base that has not been mixed with flavors or active ingredients, it is noted that the claims are to granules "comprising" conventional gum base. The presence of sorbitol and aspartame are not excluded from Applicant's "conventional" gum base. As Yang teaches "conventional" gum base elastomers and elastomer plasticizers for inclusion in his invention, the teachings of Yang are considered to meet the instant claims.
- 36. Applicant argues that mixing of different gum granules is not in focus in Yang (Remarks, p. 13).
- 37. This argument is not persuasive. Yang specifically teaches the mixing of different gum granules for reasons including, but not limited to, providing different release of flavors, improved stability of drugs, or a multiplicity of colors in the final chewing gum product (Yang col. 11 lines 49-65).
- 38. Applicant argues the instant invention is novel over Athanikar et al. (Remarks, p. 13).
- 39. The Examiner notes that Applicant has included this argument in the Remarks section pertaining to the 102 rejections. Athanikar et al. was used for a 103 rejection of claims 23 and 24, not for a 102 rejection of any claims.

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40. Applicant argues that the advantages of the instant invention arise from having a stable gum base mix (Remarks, p. 14).

- 41. These remarks are not convincing as to render the claimed invention unobvious over the teachings of the prior art. Applicant refers to the "universal gum base mix" as providing advantages. However, there is no "universal gum base mix" in the instant claims. For argument's sake, if the claimed "conventional" gum base is understood to be the "universal" gum base to which Applicant now refers, it is still unclear how Applicant's claimed invention is unobvious over the teachings of Yang, where traditional gum base ingredients including flavors, colors, sweeteners, etc., may, or may not, be present in the composition as desired by the artisan.
- 42. The alleged advantage of "once and for all" approval by authorities is also irrelevant to the claimed invention (Remarks, 14). No authority is going to approve a composition comprising a "conventional" gum base, or the "conventional" gum base itself, where no ingredients in the "conventional" gum base are defined any further than "natural resins" or "wax."
- 43. Applicants alleged advantages (Remarks, pp. 14-15) are provided for by Yang, where it is stated that different granulations may be blended in order to provide a different release of flavors, improved stability of drugs, or a multiplicity of colors, for example (Yang col. 11 lines 49-65). It is unclear how these teachings of Yang differ from the alleged advantage of e.g. shifting to another product. In providing the different blends as taught by Yang one is shifting to another product and, for example, adjusting the chew profile by providing different flavor release.

44. Applicant argues that the advantages of the instant invention arise from a feeding line of conventional gum base (Remarks, p. 15).

- 45. This argument is not persuasive. There is no indication in the instant claims that there is any such "feeding line" in Applicant's invention. Further, the precise constitution of the "conventional" gum base to which Applicant continues to refer is poorly defined. Therefore, it cannot be said that the prior art does not teach or suggest the invention as instantly claimed.
- 46. It is noted that the double patenting rejections were not addressed in the Remarks beyond noting that they will be considered upon indication of allowable subject matter.

#### Conclusion

47. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIKKI H. DEES whose telephone number is (571)270-3435. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/N. H. D./

Nikki H. Dees Examiner Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781